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10/827,307	04/20/2004	Michael B. Zemel	31894-202097	2558
26694	7590	12/28/2007	EXAMINER	
VENABLE LLP			WEBMAN, EDWARD J	
P.O. BOX 34385			ART UNIT	
WASHINGTON, DC 20043-9998			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/827,307

**Applicant(s)**

ZEMEL ET AL.

**Examiner**

Edward J. Webman

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 10-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-17, 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Prosecution is reopened in view of a finding of new grounds of rejection:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10-17, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over:

Summerbell et al (1998), of record, as evidenced by Wikipedia [1]; Dietary Supplement Fact Sheet: Calcium [2], of record, and Ask A Scientist: IU (International Unit) [3].

In their randomized controlled trial of novel, simple, and well supervised weight reducing diets in outpatients, Summerbell et al (1998) teach a method comprising in combination, during a period of time as in 16 weeks (see the abstract on page 1487)

(a) administering one or more servings of one or more calcium-containing products such as milk, either full-cream (same as cow's whole milk, Wikipedia [4]) or semi-skimmed (same as cow's low fat milk, Wikipedia [4]) and unsweetened yoghurt to obese patients suffering from at least Grade I obesity, with a BMI value of at least about 25.0, such as greater than 27, and thereby inducing a metabolic change, such as weight loss (see the abstract on page 1487 and page 1488 of Summerbell et al; and original claim 3 in the instant application), and

(b) restricting the obese individuals to a caloric intake below ad lib of about 200 to about 2500 kcal per day, such as 816 kcal daily {i.e., the **Milk only** group was restricted to milk products - a variable combination of full cream or semi-skimmed milk and unsweetened yoghurt to provide the energy equivalent of the control diet, which is 3.4 MJ daily (*Interventions* section on page 1488 of Summerbell et al), wherein 3.4 MJ is 816 kcal, using the ratio of the "Energy" units given in both K: cal and K J in the "Milk Composition Analysis" table of the Wikipedia}, wherein the individuals lost weight over the 16 weeks (i.e., about 4 months).

The mean weight loss for the **Milk only** group was 11.2 kg in 16 weeks. See page 1489, first column, first paragraph. Moreover, Table 1 on page 1488 also shows 11 obese patients in the Milk only group, wherein 2 were males and 9 were females.

However, Summerbell et al do not explicitly state the amount of calcium per day and do not explicitly indicate the number of servings of the dairy products per month.

Nevertheless, Summerbell et al teach that the **Milk only** group members were administered only whole milk or low fat milk and unsweetened yoghurt as sources of energy equivalent of the control diet, which is 3.4 MJ (816 kcal) daily.

Given that whole milk has the lowest amount of calcium content as compared to low fat milk and plain yoghurt, as shown by the Dietary Supplement Fact Sheet: Calcium [2], a conservative estimate of the total calcium content of the milk diet of the **Milk only** group administered can be derived from the known data as shown below and is greater than 1484 mg, which is within the claim recited limit of at least about 773 mg of calcium per day.

At least 1484 mg of calcium have been administered daily to those obese patients in the Milk only group in the teachings of Summerbell et al, and this number was arrived by converting the data for the whole milk only supplying the allowed 3.4 MJ (or 816 kcal), since it is known that both low fat milk and unsweetened yoghurt will provide more calcium for less energy as shown by the Dietary Supplement Fact Sheet. The conversion factors and logic for derivation are as follow:

i) cow's whole milk has 66 kcal/100 grams (Milk Composition Analysis table, Wikipedia [1]);

ii) cow's whole milk has 120 iu calcium in 100 grams (Milk Composition Analysis table, Wikipedia [1]);

iii) allowed total energy by Summerbell et al is 3.4 MJ per day {i.e., 816 kcal/day since  $66 \text{ K cal} = 275 \text{ K J}$ } (see Interventions section on page 1488 of Summerbell et al and Milk Composition Analysis table, Wikipedia [1]);

iv) 500 IU of calcium is at least 500 mg of calcium daily for an adult in UK and UN (Ask A Scientist: IU [3]), thus 120 iu calcium per 100 grams of cow's whole milk in (ii) above constitutes a conservative[5] estimate of 120 mg of calcium in 100 grams of whole milk.

Therefore, 3.4 MJ (816 kcal)/day amount of milk product required by Summerbell et al must have at least 1484 mg of calcium per day  $[816/66 \times 120]$ . This amount of calcium is conservative estimate, since the diet is supposed to contain a variable combination of whole milk with yoghurt or low fat milk with yoghurt, all variations of which will contain more calcium/gram than whole milk alone. Thus, the number is the lowest possible amount of calcium that could have been administered to the Milk only group members per day.

As to the number of servings, it would seem that one of ordinary skill in the art would be able to readily envisage at least 3 servings per day, as is being conventional, i.e., breakfast, lunch and dinner, since the **Milk only** group was restricted to milk products only for energy. Thus, at a minimum, it would seem that at least 3 servings per day in minimally 28 days or maximally 31 days in a month would result in a range of 84 to 93 servings, which range is within the "at least about 57 servings of dairy per month," recited by the instantly claimed invention.

It would have been *prima facie* obvious to one of ordinary skill in the art to apply the milk diet taught by Summerbell et al to obese female individuals suffering from at least Grade I obesity, with a BMI value of at least about 25.0 in need of losing weight for a period of time, such as about 4 months, by administering the milk/yoghurt combination diet constituting a total energy level of 3.4 MJ (or 816 Kcal) per day, since the reference teaches the method as being simple and successful for losing weight in 4 months in both obese men and obese women. Moreover, it would have been obvious to administer at least about 57 servings of dairy per month absent criticality, because the milk diet constituted consuming only dairy products (i.e., milk and yoghurt combination noted above) for the entire duration of about 4 months (i.e., 16 weeks). It would have been routine experimentation for one of ordinary skill in the art to divide the total energy allotment of the dairy products for a day into various portions or at least into three or more portions, as may be convenient to the patient and since meals generally are served three times daily, thereby constituting more than at least 57 servings per month with the reasonable expectation that the patients will lose weight on the milk only diet as taught by the reference.

As to the claimed calcium-containing foods other than milk, it would be an obvious expedient to use them as an alternative to milk in the method of Summerbell et al to achieve the beneficial effect of the nutritional value in addition to calcium in these foods.

[1] Milk in Wikipedia ( [http://en.wikipedia.org/wiki/Whole\\_Milk](http://en.wikipedia.org/wiki/Whole_Milk) )

[2] Dietary Supplement Fact Sheet: Calcium,  
<http://dietary-supplements.info.nih.gov/factsheets/calcium.asp>  
listed in the PTOL-892 mailed June 21, 2006)

[3] Ask A Scientist, <http://www.newton.dep.anl.gov/askasci/chem99/chem99135.html>

[4] See Varieties and brand section of the Milk in Wikipedia, wherein it is explained that "full cream" is "whole" cow's milk in US and UK, and "semi-skimmed" is "reduced fat" or "low fat" cow's milk.

[5] Conservative number since, the "Ask A Scientist: IU" indicates the National Academy of Sciences - U.S. for Calcium Corresponds to 800 mg of calcium for adults. Thus, using NAS IU will give higher amount of calcium per same amount of whole milk than using IU for UK.

Claims 1-7, 10-17, 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 10, 19, the phrase "below ad lib in a range of about 200 to about 2500 kcal per day" is unclear. On page 9 lines 8-14 applicants disclose the range in the context of a reduced caloric intake compared to ad lib. Is the implication here that "ad lib" is a caloric intake that can exceed the claimed range?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7, 10-17, 19-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Zemel et al (FASEB J. , June 2000, 14(9) 1132-8.

Zemel et al. teach: 1) the body mass index (BMI) of the women of the NHAMES III study was  $25.7 \pm 0.4$  (Table 1 at p. 1134), thus the women have Grade I obesity according to the specification at p. 10, paragraph 43; 2) the women had an energy intake of  $1896 \pm 68$  kcal/day (Table 1 at p. 1134); 3) the 3rd quartile of women had a calcium intake of  $773 \pm 28$  mg/day and  $57.2 \pm$  servings/month (Table 4 at p. 1137). Zemel et al additionally teach the 4th quartile of women had a calcium intake of  $1346 \pm 113$  mg/day and  $102.8 \pm 3.6$  servings/month (Table 4 at p. 1137). Reduction of adiposity, reduction of adipocyte mass and stimulation of lipolysis is disclosed (abstract). Thermogenesis is specified (Figure 5).

Claims 1-7, 10-17, 19-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the claim amendment filed on 10/18/06, claims 1, 10, and 19 were amended to recite the limitations "administering... an amount of dietary calcium . . . at least about 773 mg per day" and "at least about 57 servings of dairy per month." Similarly, claims 5-7 specify "less than about 400 mg/day", "less than about 773 mg/day" and "at least about 1346 mg/day." In the accompanying remarks at p. 7, top, applicant points to Table 4 of the specification (p. 18) as providing descriptive support for this limitation. Table 4 is reproduced below with the relevant portion highlighted. Because the limitation of "at least about" with respect to both 773 and 57

provides for variation (e.g., 10% of 773 or 57) that is greater than that provided in Table 4, I would say these limitations introduce new matter into the claims.

TABLE 4			
Effects of dietary calcium, and dairy intake on the risk of being in the highest quartile of body fat for women <sup>a</sup>			
Quartile of calcium and dairy consumption	Calcium intake (mg/day: mean $\pm$ SEM)	Dairy consumption (servings, month: mean $\pm$ SEM)	Odds ratio of being in the highest body fat quartile
1	255 $\pm$ 20	14.4 $\pm$ 1.9	1.00
2	484 $\pm$ 13	38 $\pm$ 1.3	0.75 (0.13, 4.22) <sup>b</sup>
3	773 $\pm$ 28	57.2 $\pm$ 1.0	0.40 (0.01, 3.90) <sup>b</sup>
4	1346 $\pm$ 113	102.8 $\pm$ 3.6	0.16 (0.03, 0.88) <sup>b</sup>

<sup>a</sup> Model is controlled for race/ethnicity and activity level, with age and caloric intake as continuous covariates.

<sup>b</sup> 95% Confidence interval in parenthesis

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633.

The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR



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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**EDWARD J. WERMAN  
PRIMARY EXAMINER  
GROUP 1500**